FEB 0 7 2013

510(k) Summary
Maxim Surgical X-Treme Interbody Fusion System
Premarket Notification

SUBMITTED BY	Maxim Surgical 1565 North Central Expressway, Suite 200 Richardson, Texas 75080
ESTABLISHMENT REGISTRATION NUMBER	Pending
OWNER/OPERATOR NUMBER	Pending
CONTACT PERSON	Chris Reeg President Maxim Surgical Phone: 214-564-1350 Fax: 972-692-8934
SUBMISSION PREPARED BY	Lisa Peterson Kaedon Consulting, LLC Phone: 512-507-0746
DATE PREPARED	January 9, 2013
CLASSIFICATION NAME	Intervertebral Body Fusion Device
DEVICE CLASS	Class II
REGULATION NUMBER	888.3080 (Product Code ODP)
COMMON NAME	Intervertebral Fusion Device with Bone Graft, Cervical
PROPRIETARY NAME	Maxim Surgical X-Treme Interbody Fusion System
IDENTIFICATION OF PREDICATE DEVICE(S)	Predicate devices include various cleared interbody fusion systems: - Zimmer Spine: BAK/C (P980048) - LDR Spine: MC+ (K043479, K091088) - Eminent Spine: Eminent Spine Interbody Fusion System (K090064) - SpineNet, LLC: Daytona Anterior Cervical Cage (K110733)

DEVICE DESCRIPTION
The Maxim Surgical X-Treme Interbody Fusion System is a cervical interbody fusion system comprised of neutral and lordotic cages in two footprints with varying heights designed to accommodate patient anatomy, and may be implanted as a single device via an anterior approach.

The Maxim Surgical X-Treme Interbody Fusion System implant components are made of polyether ether ketone (PEEK Zeniva ZA-500) that conforms to ASTM F2026. Additionally, the devices contain tantalum markers (ASTM F560) to assist the surgeon with proper placement of the device.

The Maxim Surgical X-Treme Interbody Fusion System is implanted using a combination of device specific and universal class I instruments manufactured from stainless steel materials that conform to ASTM F899.

INDICATIONS
When used as a cervical intervertebral body fusion device, the Maxim Surgical X-Treme Interbody Fusion System is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-TI disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS
The purpose of this premarket notification is to obtain clearance to market the Maxim Surgical X-Treme Interbody Fusion System. The Maxim Surgical X-Treme Interbody Fusion System is comprised of neutral and lordotic cages in two footprints with varying heights designed to accommodate patient anatomy, and may be implanted as a single device via an anterior approach.

The Maxim Surgical X-Treme Interbody Fusion System implant components are made of polyether ether ketone (PEEK Zeniva ZA-500) that conforms to ASTM F2026. Additionally, the devices contain tantalum markers (ASTM F560) to assist the surgeon with proper placement of the device.

The subject system has similar technological characteristics as the predicate devices identified above. Specifically, the following characteristics support this conclusion:

- Intended for use at one level from the C2-C3 disc to the C7-TI disc for the treatment of degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms.
- Substantially equivalent results of non-clinical testing relative to static and dynamic testing (per ASTM F2077-11), subsidence (per ASTM F2267-04), and expulsion (per ASTM Draft Standard F-04.25.02.02)

DISCUSSION OF NON-CLINICAL TESTING
The following non-clinical tests were conducted:
- Static and dynamic compression testing, conducted in accordance with ASTM F2077-11
- Static and dynamic torsion testing, conducted in accordance with ASTM F2077-11
- Subsidence testing, conducted in accordance with ASTM F2267-04
- Expulsion testing, conducted in accordance with ASTM Draft Standard F-04.25.02.02

CONCLUSIONS
The subject and predicate device(s) share the same intended use, primary implant design and equivalent material of manufacture. The non-clinical mechanical test results demonstrate that any minor differences do not impact device performance as compared to the predicates and demonstrate that the Maxim Surgical X-Treme Interbody Fusion System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Maxim Surgical
% Mr. Chris Reeg
President
1565 North Central Expressway, Suite 200
Richardson, TX 75080

Letter dated: February 7, 2013

Re: K123206
Trade/Device Name: Maxim Surgical X-Treme Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: January 16, 2013
Received: January 16, 2013

Dear Mr. Reeg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K123206

Device Name: **Maxim Surgical X-Treme Interbody Fusion System**

Indications for Use:

When used as a cervical intervertebral body fusion device, the Maxim Surgical X-Treme Interbody Fusion System is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-TI disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Stephanie Bechtold -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K123206